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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,168	09/30/2005	Peter Terness	4121-176	2833

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,168	TERNESS ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-21,23 and 24* is/are pending in the application.

4a) Of the above claim(s) *7,11-21,23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Terness et al.

1. Applicant's response filed on 6/16/2008 is acknowledged. Claims 1-3, 6-21, 23 and 24 are pending. Claims 4, 5 and 22 have been cancelled. Claims 7 and 11-21, 23 and 24 have been withdrawn from consideration. Claims 1-3, 8 and 9 have been amended.

2. Claims 1-3, 6 and 8-10 are under examination.

Specification

3. The objection to the specification because the brief Description of the Drawings does not reference each of the Figures is maintained because applicant's amendment to the specification was not made to the original disclosure. The amendment to the specification should be made to the original disclosure, not the published application (PG Pub).

Objections Withdrawn

4. The objection to claims 2, 3 and 8 is withdrawn in view of applicant's amendment to the claims.

Rejections Withdrawn

5. The rejection of claims 1-5 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of applicant's amendment to the claims.

6. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the phrase "functional derivative or active fraction thereof" is withdrawn upon further consideration.

7. All previous art rejections are withdrawn in view of applicant's amendment to the claims.

Rejections Maintained

Claim Rejections - 35 USC § 112, 1st paragraph

8. The rejection of claims 1-3, 6 and 8-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

It is noted that claim 1, which was not previously rejected, is included in this rejection due to applicant's amendment to the claim.

The response states that applicants have combined claims 4 and 5 with claim 1, the amended claim 1 more clearly defines characteristics of the isolated surface glycoproteins. The response states that applicants are in possession of the recombinant protein because as of the filing date of the present application, one of ordinary skill in the art could easily design probes to screen the genomic or cDNA libraries based upon the various amino acid sequences disclosed. In addition, applicants submit that the specification teaches at least two monoclonal antibodies against ACA, therefore, one of ordinary skill in the art could screen an expression library such as a human phage display cDNA library and select clones expressing ACA. One

of ordinary skill in the art could use bioinformatics to find the DNA sequence of the gene encoding ACA in already existing gene banks or protein banks.

Applicant's arguments have been carefully considered but are not persuasive. The amendment to the claims does not overcome the rejection. As indicated in the previous office action, applicants are claiming a genus of molecules having part or all of the characteristics recited in the claims, as well as functional derivative, and active fraction thereof, while the specification only discloses one ACA glycoprotein (a single species) within the genus, i.e. the surface glycoprotein ACA that is characterized by all the features recited in the claims. The specification does not disclose any protein that only has part of the features recited in the claims. While one skilled in the art may identify all the molecules that comprise at least one recited SEQ ID NO, one skilled in the art would not be able to identify without further experimentation which of those molecules would also have the molecular weight of about 65 or 68 kD, the isoelectric point of pH 5.5 and other characteristics recited in the claims. The specification does not disclose a protein that comprises only one, but not other sequences selected from SEQ ID NOs.1-11, and is a GPI-anchored protein having the recited properties. The specification does not disclose any biological function or activity of the claimed molecules including the ACA glycoprotein that has all the features recited in the claims. The general knowledge in the art does not provide any indication of how the structure of one glycoprotein having all the recited characteristics is representative of the broadly claimed glycoproteins having part of the characteristics. In the absence of structural characteristics that are shared by members of the genus, one of skill in the art would

reasonably conclude that applicant was not in possession of the claimed genus because description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim. With regard to the functional derivatives and active fragments, applicant does not appear to have reduced to practice any biological derivative or active fragment of an ACA glycoprotein. Neither has applicant provided sufficient descriptive information such as definitive structural features that are common to the genus of derivatives or active fragments. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of a single species is insufficient to describe a highly variant genus. Therefore, only the ACA glycoprotein protein have all the features recited in the claims (GPI anchored, obtained from human blood, isoelectric point, molecular weight, comprising SEQ ID NO.1-11), but not the full breadth of a surface glycoprotein ACA, functional derivatives, and active fragments thereof meet the written description provision of 35 U.S.C. § 112 first paragraph.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st "Written Description" (Revision 1, 3/25/2008), particularly the Example 5, wherein a partial protein structure is disclosed. Claim 1 of the Example 5, which recites all the identifying characteristics of the protein, as well as the isolation method, meets the written description requirement. The instant situation is similar to the fact pattern disclosed in the Example 5. In order to satisfy the written description

requirement, claims must be amended to recite all the identifying characteristics and the isolation methods.

With respect to the claimed recombinant protein, as indicated in the previous office action, in order to make a recombinant protein, one would need to have the sequence of the DNA encoding the protein. The court stated "since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicant's contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties." *See in re Wallach 71 USPQ2d 1939 (Fed. Cir. 2004).* The court stated "Given the amino acid sequence, one can determine the chemical structure of all nucleic acid molecules that can serve the function of encoding that sequence. Without that sequence, however, or with only a partial sequence, those structures cannot be determined and the written description requirement is consequently not met". In the instant case, applicants have not provided any evidence that the full amino acid sequence of a protein can be deduced from a partial sequence and the limited additional physical characteristics that they have identified. Without the full sequence, one skilled in the art would not conclude that applicants are in possession of the DNA encoding the protein, and as such applicants are not in possession of the recombinant protein. Furthermore, the proposal to screen and find the DNA is not a practical way to describe the claimed molecule. Applicants are further directed to the claim 2 of the

Example 5 of the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st "Written Description" (Revision 1, 3/25/2008).

Because of these reasons, the rejection is deemed proper and is therefore, maintained.

Claim Rejections - 35 USC § 112, 1st paragraph

9. The rejection of claims 1-3, 6 and 8-10 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the surface glycoprotein ACA, a salt thereof that is characterized by all the features recited in claims 2-6 and 8-10, i.e. (a) it is GPI-anchored on the cell surface; (b) it can be removed from the cell membrane by treatment with PI-PLC; (c) its GPI-anchor is characterized by a non-acetylated inositol ring and diacyl glycerol as lipid tail of the anchor; (d) it has an isoelectric point of pH 5.5; (e) it is present on progenitor cells, granulocytes, monocytes, B-cells (but not T-cells), melanocytes, and other cells; (f) it is preferentially expressed during cell division and in tumor cells; (g) it has a molecular weight of 65 or 68 kD when analyzed by SDS PAGE under reducing conditions, and (h) it contains the amino acid sequences SEQ ID NO.1-11, does not reasonably provide enablement for any and all surface glycoprotein ACA, functional derivatives, active fragments, and recombinant proteins thereof that is characterized by the features disclosed in claims 2-5 and 8-10 is maintained.

It is noted that claim 1, which was not rejected previously, is included in this rejection due to applicant's amendment to the claim.

The response states that applicants have combined claims 4 and 5 with claim 1, the amended claim 1 more clearly defines characteristics of the isolated surface glycoproteins. The response states that applicants are in possession of the recombinant protein because as of the filing date of the present application, one of ordinary skill in the art could easily design probes to screen the genomic or cDNA libraries based upon the various amino acid sequences disclosed. In addition, applicants submit that the specification teaches at least two monoclonal antibodies against ACA, therefore, one of ordinary skill in the art could screen an expression library such as a human phage display cDNA library and select clones expressing ACA. One of ordinary skill in the art could use bioinformatics to find the DNA sequence of the gene encoding ACA in already existing gene banks or protein banks.

Applicant's arguments have been carefully considered but are not persuasive. As indicated in the previous office action, one cannot extrapolate the teachings of the specification to the scope of the claims because the specification only teaches a single GPI-anchored surface glycoprotein ACA that is isolated from blood and comprises all the characteristics recited in the claims i.e. all SEQ ID NOS.1-11, the isoelectric point of 5.5 and the molecular weight of 65 or 68 kD, and the claims are broadly drawn to any GPI anchored proteins having part of the features recited in the claims, functional derivatives, and active fragments thereof. The specification does not disclose any molecule that comprises only part of the characteristic. The specification does not disclose that the molecules having part of the characteristics would have the same function. Without knowing the function, one skilled in the art would not know how to use

the full scope of the molecules as broadly claimed. Moreover, the specification does not disclose any functional derivative, and active fragment of the ACA. Since the specification does not disclose any biological activity and the function of the ACA protein, one skilled in the art would not know how to make and use the functional derivative and active fragments of the ACA. Regarding the recombinant protein, applicants have not provided any evidence that the full amino acid sequence of a protein can be deduced from a partial sequence and the limited additional physical characteristics that they have identified. Without the full sequence, one skilled in the art would not conclude that applicants are able to make the recombinant protein. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make and use the broadly claimed surface glycoproteins, active fragments, functional derivatives thereof that have the recited features. It would require undue experimentation for one skilled in the art to perform the full scope of the invention. Because of these reasons, the rejection is deemed proper and is therefore maintained.

New Grounds of Objection

Claim Objections

10. Claims 1-3, 6, and 8-10 are objected to because of the following informalities: the amended claim 1 recites “Table-US-0004 (SEQ ID NO:1) (see line 6), which appears to be a typographical error. Moreover, the last sequence (see part (k) of the claim) lacks SEQ ID NO. Appropriate correction is required.

Conclusion

11. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
9/5/08

/Christopher H Yaen/
Primary Examiner, Art Unit 1643